



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mark A. Tracy, Kevin L. Ward and Warren E. Jaworowicz
Application No.: 10/773,124 Group Art Unit: 1615
Filed: February 5, 2004 Examiner: Not Assigned
Confirmation No.: 3258
Title: METHOD OF PRODUCING SUBMICRON PARTICLES OF A LABILE AGENT AND USE THEREOF

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
7/7/04	<i>Christina MSweeney</i>
Date	Signature
<i>Christina MSweeney</i>	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. 09/321,091, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Susan M. Abelleira

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Concord, MA 01742-9133

Dated: July 7, 2004

PTO-1449 REPRODUCED

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

July 7, 2004

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
1733.1045-008APPLICATION NO.
10/773,124FIRST NAMED INVENTOR
Mark A. TracyFILING DATE
February 5, 2004EXAMINER
Not AssignedCONFIRMATION NO.
3258GROUP
1615

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	5,307,640	03 MY 94	Fawzy, <i>et al.</i>
	AB	5,475,984	19 DEC 95	Fermani, <i>et al.</i>
	AC	5,399,363	21 MAR 95	Liversidge, <i>et al.</i>
	AD	5,145,684	08 SEP 92	Liversidge, <i>et al.</i>
	AE	5,518,187	21 MAY 96	Bruno, <i>et al.</i>
	AF	5,591,456	07 JAN 97	Franson, <i>et al.</i>
	AG	5,817,343	06 OCT 98	Burke
	AH	5,711,968	27 JAN 98	Tracy, <i>et al.</i>
	AI	5,716,644	10 FEB 98	Zale, <i>et al.</i>
	AJ	5,667,808	16 SEP 97	Johnson, <i>et al.</i>
	AK	5,674,534	07 OCT 97	Zale, <i>et al.</i>
	AA2	5,656,297	12 AUG 97	Bernstein, <i>et al.</i>
	AB2	5,540,937	30 JUL 96	Billot, <i>et al.</i>
	AC2	5,019,400	28 MAY 91	Gombotz, <i>et al.</i>
	AD2	5,654,010	05 AUG 97	Johnson, <i>et al.</i>
	AE2	5,912,015	15 JUN 99	Bernstein, <i>et al.</i>
	AF2	5,922,253	13 JUL 99	Herbert, <i>et al.</i>
	AG2	5,534,270	09 JUL 96	De Castro
	AH2	6,444,223	03 SEP 02	Tracy, <i>et al.</i>
	AI2	6,514,533	04 FE 03	Burke, <i>et al.</i>
	AJ2			
	AK2			
	AA3			
	AB3			
	AC3			

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION July 7, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1733.1045-008		APPLICATION NO. 10/773,124	
	FIRST NAMED INVENTOR Mark A. Tracy		FILING DATE February 5, 2004	
	EXAMINER Not Assigned		CONFIRMATION NO. 3258	GROUP 1615

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL	WO 95/31973	30 NOV 95	Eastman Kodak Company		
	AM	WO 90/13780	15 NOV 90	Enzytech, Inc.		
	AN	WO 90/13285	15 NOV 90	Enzytech, Inc.		
	AO	WO 95/29664	09 NOV 95	Alkermes Controlled Therapeutics, Inc.		
	AP	WO 97/42940	20 NOV 97	Alkermes, Inc.		
	AQ	EP 0330180 A1	30 AUG 89	Biomaterials Universe, Inc.		
	AL2	EP 0499299 A2	19 AUG 92	NanoSystems L.L.C.		
	AM2					
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EXAMINER	DATE CONSIDERED
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	FIRST NAMED INVENTOR Mark A. Tracy		FILING DATE February 5, 2004	
	EXAMINER Not Assigned		CONFIRMATION NO. 3258	GROUP 1615

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	"Drug Nanocrystals for Improved Drug Delivery of Poorly Water Soluble Compounds", Presentation at CRS Meeting, Kyoto Japan 7/11/1996, Pages 1-50 by G. Liversidge and E. Cooper.
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EXAMINER	DATE CONSIDERED
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